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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,012	04/13/2004	Micheal Patrick Dillon	R0130D-CON	4690

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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,012	DILLON ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-62* is/are pending in the application.

4a) Of the above claim(s) *53 and 55-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-52 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 48-62 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 10, 2006 has been entered.

Election/Restrictions

Applicants' election without traverse of Group I, and the species of Example 3 in step 4 on page 49 (reproduced below), in the reply filed on

December 16, 2004 was acknowledged in the previous Office Action.

Step 4

The requirement was deemed proper and made FINAL in the previous Office Action.

Claims 53 and 55-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in the reply filed on December 16, 2004.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these objections will not be addressed.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on April 27, 2006.

Terminal Disclaimer

The terminal disclaimer filed on May 10, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,756,395 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Amendment

The Declaration under 37 CFR 1.132 filed May 10, 2006 by Counde O-Yang is insufficient to overcome the rejection of claims 48-52 and 54 based upon 35 USC 103 as set forth in the last Office action

because: (1) the showing is directed to, or relying on, blood pressure changes only and not treating incontinence (see test and data in paragraphs [194]-[200] on pages 56-58, respectively of the instant specification) as well as the affects blood pressure changes (see test and data in paragraphs [201]-[205] on pages 58-59, respectively of the instant specification) to show unexpected, beneficial and unobvious results; (2) the various representative points (e.g., square?, triangle?, circle?) on the graphs in Figures 1 and 2 were not distinguishable or legible; and (3) the showing was not commensurate in scope of the instant claimed invention. *In re Greenfield*, 197 U.S.P.Q. 227 (1978) and *In re Lindner*, 173 U.S.P.Q. 356 (1972). Also see M.P.E.P. 716.02(d).

In regard to Applicants' showing not commensurate in scope, Applicants have only compared one of the compounds of the instant claimed invention with only one compound of Cournoyer et al. By comparing the

compounds found in Table 1 of the instant specification starting at page 19 (reproduced below) with the compounds of Cournoyer et al. (relevant columns reproduced below), the following table illustrates some of the other compounds which should also have been compared to persuasively show that the instant claimed compounds have unexpected, beneficial and unobvious results, as alleged by Applicants, over the compounds of Cournoyer et al. in treating urinary incontinence while not increasing blood pressure. See, for example, the table below.

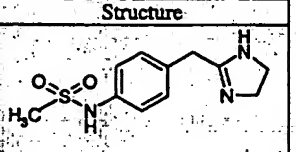
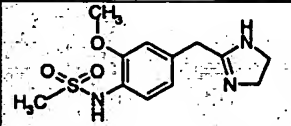
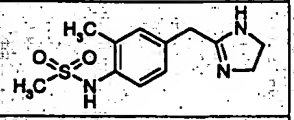
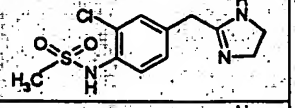
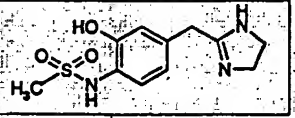
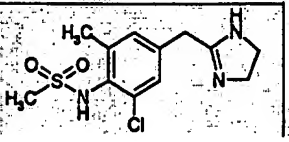
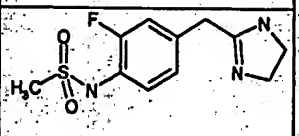
Applicants' Compounds	Cournoyer et al. Compounds
Compound 1 ---------▶	The Compound in column 39, lines 29-31
Compound 2 ---------▶	The Compound in column 40, lines 10-12
Compound 3 ---------▶	The Compound in column 39, lines 16-18
Compound 4 ---------▶	The Compound in column 39, lines 38-40
Compound 5 ---------▶	The Compound in column 39, lines 32-34
Compound 19 ---------▶	The Compound in column 39, lines 22-24
Compound 40 ---------▶	The Compound in column 39, lines 46-48

Instant Compounds found on pages 19, 21 and 24, respectively, of the instant specification that are embraced by independent claim 48 follow.

[83] Some of the representative Compounds of Formula I are shown in Table 1 below:

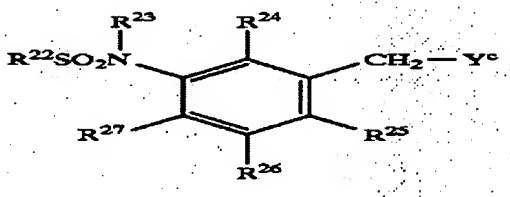
Table of Representative Compounds of Formula I:

TABLE 1

	Name (Autonom®)	Example	Structure
1	*N*-[4-(4,5-Dihydro-1*H*-imidazol-2-ylmethyl)-phenyl]-methanesulfonamide;	2	
2	*N*-[4-(4,5-Dihydro-1*H*-imidazol-2-ylmethyl)-2-methoxy-phenyl]-methanesulfonamide;	2	
3	*N*-[4-(4,5-Dihydro-1*H*-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide	2	
4	*N*-[2-Chloro-4-(4,5-dihydro-1*H*-imidazol-2-ylmethyl)-phenyl]-methanesulfonamide	3	
5	*N*-[4-(4,5-Dihydro-1*H*-imidazol-2-ylmethyl)-2-hydroxy-phenyl]-methanesulfonamide	2	
19	*N*-[2-Chloro-4-(4,5-dihydro-1*H*-imidazol-2-ylmethyl)-6-methyl-phenyl]-methanesulfonamide	1	
40	N-[4-(4,5-Dihydro-1H-imidazol-2-ylmethyl)-2-fluoro-phenyl]-methanesulfonamide	4	

Compounds of Cournoyer et al. found in Columns 39 and 40.

39



wherein Y^c is 2-imidazoline, and

R^{22}	R^{23}	R^{24}	R^{25}	R^{26}	R^{27}
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)	H	CH_3	H	H	H
CH_3 (N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)	H	H	H	H	CH_3
CH_3 N-[3-chloro-5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide	H	H	H	Cl	CH_3
CH_3 (N-[3-bromo-5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)	H	H	H	Br	CH_3
CH_3 (N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methoxy-phenyl]-methanesulfonamide)	H	H	H	H	OCH_3
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-phenyl]-methanesulfonamide)	H	H	H	H	H
CH_3 (N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-hydroxy-phenyl]-methanesulfonamide)	H	H	H	H	OH
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-4-fluoro-phenyl]-methanesulfonamide)	H	H	F	H	H
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-N-methyl-methanesulfonamide)	CH_3	CH_3	H	H	H
CH_3 (N-[2-chloro-3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-phenyl]-methanesulfonamide)	H	Cl	H	H	H
CH_3 (N-[6-(4,5-dihydro-1H-imidazol-2-ylmethyl)-biphenyl-2-yl]-methanesulfonamide)	H	C_6H_5	H	H	H
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2,4-dimethyl-phenyl]-methanesulfonamide)	H	CH_3	CH_3	H	H
CH_3 (N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-fluoro-phenyl]-methanesulfonamide)	H	H	H	H	F
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2,6-dimethyl-phenyl]-methanesulfonamide)	H	CH_3	H	H	CH_3
CH_3 (N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2,6-dimethyl-phenyl]-methanesulfonamide)	H	CH_3	H	CH_3	H
CH_3 (N-[3-(3H-imidazol-4-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)	H	$CH{=}CH_2$	H	H	H
CH_3	H	C_2H_5	H	H	H

40

-continued

R^{22}	R^{23}	R^{24}	R^{25}	R^{26}	R^{27}
methanesulfonamid)					
CH_3	H	H	H	OCH_3	H
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-5-methoxy-phenyl]-methanesulfonamide)					
CH_3CH_2	H	H	H	H	CH_3
(ethanesulfonic acid[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl)-amide)					
CH_3	H	OCH_3	H	H	H
(N-[3-4,5-dihyro-1H-imidazol-2-ylmethyl)-2-methoxy-phenyl]-methanesulfonamide)					

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A

terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-52 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8, 10, 12-14, 18, 20, 27-30, 32, 44-47, 56-58, 60 and 64 of U.S. Patent No. 5,952,362 (Cournoyer et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are positional isomers of the compounds claimed in U.S. Patent No. 5,952,362.

In U.S. Patent No. 5,952,362, see claim 1 (columns 124-125) and especially claim 27 (column 127) and claim 44 (column 128). The sulfonamide group in the compounds found in U.S. Patent No. 5,952,362 is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer). Nothing unobvious is seen in substituting the

known claimed isomer for the structurally similar isomer, as claimed in U.S. Patent No. 5,952,362 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris,* 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds claimed in U.S. Patent No. 5,952,362, to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Cournoyer et al. {U.S. Pat. 5,952,362} for reasons set forth below.

The applied reference has a common inventor (i.e., Counde O'Yang) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this

application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournoyer et al. {U.S. Pat. 5,952,362}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim imidazolin-2-yl-methylphenyl compounds. Cournoyer et al. teach imidazolin-2-yl-methylphenyl compounds that are structurally similar to the instant claimed compounds. See in Cournoyer et al., for example, formula 1 in columns 7 and 8 and especially the sixth compound listed in the table in column 39.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of Cournoyer et al. and the compounds instantly claimed is that the sulfonamide group is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Cournoyer et al., since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris,* 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds taught by Cournoyer et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

Applicants' arguments filed May 10, 2006 have been considered. Applicants argue that independent claim 48 is narrow in scope and includes only two variables (R^1

and R^4) in which R^1 is limited to alkyl and R^4 is limited to hydrogen, halo, alkyl, alkoxy and hydroxy. Applicants have cited *In re Chupp*, 2 USPQ2d 1437 (CAFC 1987) and argues "No set number of examples of superiority is required". Applicants conclude by arguing that the showing of unexpected benefit by the Rule 132 Declaration submitted on May 10, 2006 is commensurate in scope with the claims.

In response, Applicants' arguments are not persuasive. In *In re Chupp*, it states, "there is no set number of crops on which compound's superiority must be shown". Further, the Applicant in *In re Chupp*, had "canceled all but eleven claims and limited the remaining claims to a single compound". Instant independent claim 48 claims a genus of compounds, not a single compound. As stated above, M.P.E.P. 716.02(d) requires that the showing be commensurate in scope with the instant claimed invention. *In re Greenfield*, 197 U.S.P.Q. 227 (1978) and *In re Lindner*, 173 U.S.P.Q. 356

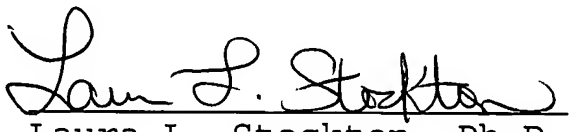
(1972) also state that the showing must be commensurate in scope with the claimed invention.

Additionally, Cournoyer et al. teach a number of imidazolin-2-yl-methylphenyl compounds which have substituents embraced by the definitions of the instant R^1 and R^4 variables as shown above in the table. In the Declaration filed on May 10, 2006, Applicants have compared only one compound and therefore, the showing is not sufficient for this reason and the others stated above. For all the reasons stated above, the rejections above are proper and are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.
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Art Unit 1626, Group 1620
Technology Center 1600

May 25, 2006